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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,892	08/18/2000	Hiroshi Izui	195942US0	6721

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EXAMINER	
LAMBERTSON, DAVID A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/641,892	IZUI ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed September 25, 2003.

Claims 1-24 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed March 26, 2003, that is not addressed in this action has been withdrawn.

Information Disclosure Statement

The information disclosure statement filed January 27, 2004 has been considered, and a signed and initialed copy of the form PTO-1449 is attached to this Office Action.

Claim Rejections - 35 USC § 112

It is noted that the Examiner inadvertently determined the scope of Enablement and Written Description too broadly in the previous Office Action. In response, the Examiner has again presented the previous rejections, more appropriately addressing the scope that is enabled and described. The rejections are treated as new rejections, although Applicant's arguments will still be addressed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 14, and 17-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection not necessitated by amendment.**

Applicant claims any microorganism with the ability to survive in medium that has reached its saturation concentration for glutamic acid content, and to produce and accumulate more glutamic acid in such an environment. The claims read on a broad genus of microorganisms that must not only survive in a medium containing a saturated amount of glutamic acid, but must also continue to produce glutamic acid in that environment.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a microorganism with the ability to survive in medium that has reached its saturation concentration for glutamic acid content, and to produce and accumulate more glutamic acid in such an environment by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings

regarding a specific *Enterobacter agglomerans* strain, AJ13355, and its capacity to continue to produce glutamic acid under conditions where glutamic acid is at a concentration that is both toxic to typical microorganisms and inhibitory to the further production of glutamic acid. The specification does not teach how to envision other microorganisms that will necessarily have the ability to survive such high concentrations of glutamic acid and still produce more glutamic acid because the specification does not disclosed what structural features within AJ13355 result in this desirable property. Specifically, there is no description of what structural characteristics (e.g., gene mutations, etc.), when present in other strains, will necessarily confer the ability to grow and produce glutamic acid in high concentrations of glutamic acid. Thus, the skilled artisan cannot envision a sufficient number of microorganisms (aside from AJ13355, or its progeny) that will necessarily have the required property of growth and further glutamic acid production in the presence of already saturating concentrations of glutamic acid.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of microorganisms with the ability to survive in medium that has reached its saturation concentration for glutamic acid content, and to produce and accumulate more glutamic acid in such an environment by disclosing structural or functional features of such a microorganism so that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of microorganisms with the ability to survive in

medium that has reached its saturation concentration for glutamic acid content, and to produce and accumulate more glutamic acid in such an environment. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 1-10, 14, and 17-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific *Enterobacter agglomerans* strain, AJ13355, does not reasonably provide enablement for any microorganism with the ability to survive in medium that has reached its saturation concentration for glutamic acid content, and to produce and accumulate more glutamic acid in such an environment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This is a new rejection not necessitated by amendment.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is any microorganism with the desired property of being able to survive in medium that has reached its saturation concentration for glutamic acid content, and to produce and accumulate more glutamic acid in such an environment. The invention requires that one of skill be able to make such an organism without empirical, undue and unpredictable trial and error experimentation; i.e., the skilled artisan must be able to recognize what structural features confer the desirable characteristic on a microorganism such that the skilled artisan can take that structural feature and create another microorganism with the desired characteristic. It is noted that the ability to "identify" a microorganism with the desired property is not equivalent to the ability to "make and use" a microorganism based on the above principle.

Scope of the invention. The scope of the invention is very broad, encompassing any microorganism with the desired property. However, there is only a description of a single specific microorganism with this property (AJ13355, and its progeny), and there is no description of a structural feature (i.e., a gene mutation) of the microorganism that specifically confers this property on the microorganism. As such, the skilled artisan cannot make the broad scope of the claimed microorganisms.

State of the Art and Level of skill in the art. The state of the art as it regards metabolic engineering of all microorganisms is very unpredictable. Support for this assertion comes from the teachings of Bailey (Science 252: 1666-1675, 1991). Bailey indicates that, "At the present, metabolic engineering is more a collection of examples than a codified science" (see for example page 1668, third paragraph, left side), suggesting that a single example of successful metabolic engineering does not indicate that the same principles or methods used in the single example are

adequate to define any other situation. This is further supported by the indication that "many studies have shown the feasibility of metabolic engineering methods without achieving the yields rates or titers required for a practical process" (see for example page 1668, third paragraph, left side). Furthermore, "the route of reactions to a desired product passes several forks where intermediates can enter alternative pathways..." and "Maximizing product formation requires that the desired route at each fork be made a priority and that traffic in alternative pathways be minimized to the extent possible without decreasing cell viability" (see page 1671, second full paragraph, right side). In this particular instance, the invention requires knowledge of a vast number of species, including what each of the enzymes for the desired activities are, whether their overexpression/deletion/etc. can be achieved with the desired yield of producing more L-glutamic acid than that which is present in the medium, to what level can these enzymes be modified without compromising the viability of the strain, how these biosynthetic pathways operate, etc. The prior art does not teach such a vast amount of information so that the skilled artisan, seeking to isolate any microorganism with the ability to produce L-glutamic acid in a medium that is already at saturation for L-glutamic acid, would be able to consult the prior art so that such a microorganism can be produced. Similarly, it would be impossible to predictably engineer every microorganism to increase the activity of an L-glutamic acid biosynthesis enzyme, or decrease the activity of a branch point enzyme, wherein such enzymes have not been adequately characterized. As a result, the skilled artisan could not turn to the prior art in order to make and use the invention as claimed without performing unpredictable trial and error experimentation.

The State of the art is further complicated by the fact that there is no description in the prior art of a structural feature that can be used to confer onto any microorganism the ability to survive in medium that has reached its saturation concentration for glutamic acid content, and to produce and accumulate more glutamic acid in such an environment. Since the skilled artisan cannot rely on the prior art to define this structural feature, the skilled artisan would be forced to consult the instant specification to make and subsequently use the instantly claimed strains.

Number of working examples and Guidance provided by applicant. Applicant only provides a single working example regarding a microorganism with the desired property of being able to survive in medium that has reached its saturation concentration for glutamic acid content, and to produce and accumulate more glutamic acid in such an environment. That example is the isolation of *Enterobacter agglomerans* strain AJ13355, and its further modification along the pathways of L-glutamic acid biosynthesis. This single example is not indicative of an ability to predictably practice the invention with regard to all microorganisms because the skilled artisan could not routinely confer the desired properties displayed by strain AJ13355 onto a different organism. In other words, the skilled artisan could not consult the instant specification on how to genetically engineer any other microorganism to both survive and produce L-glutamic acid in a medium that is already at saturation for L-glutamic acid, by modifying the biosynthetic pathway for L-glutamic acid in that organism.

Unpredictability of the art and Amount of experimentation. The art is highly unpredictable. First, there is an insufficient teaching on how to make a microorganism with the desired property of being able to survive in medium that has reached its saturation concentration for glutamic acid content, and to produce and accumulate more glutamic acid in such an environment. There is no

description of a structural component of the single example (AJ133555) that confers the desired property on the strain, therefore the skilled artisan could not confer the desired property in a different strain without undue and unpredictable trial and error experimentation. Furthermore, as set forth by the teachings of Bailey, the metabolic engineering of one organism does not equate to an ability to perform such modifications in another organism. To quote Bailey, "Further improvements in rates of amino acid synthesis and yields...depend on a better understanding of mechanisms of gene regulation and metabolite flow" (see for example page 1672, first incomplete paragraph, left side). Unless these pathways are understood in every organism, the skilled artisan cannot make or use the invention commensurate with the scope of the claims without practicing undue and unpredictable trial and error experimentation. Such experimentation would include, identifying an organism that does not have a prevalent feedback mechanism for L-glutamic acid, identifying and characterizing the entire pathway for L-glutamic acid biosynthesis for each microorganism and obtaining information regarding the level of modulation that can be achieved in the microorganism (with regard to L-glutamic acid production) without compromising the viability of the microorganism.

In conclusion, the invention as claimed entails an enormous amount of experimentation, including the biochemical characterization of L-glutamic acid biosynthesis in millions of microorganisms and understanding the level of modification that can be performed on any particular microorganism without affecting the organism's viability. The amount of experimentation is undue and unpredictable because the skilled artisan would not know whether or not there was a reasonable expectation of success in modifying any particular microorganism to produce L-glutamic acid in a medium where L-glutamic acid was already at a saturated level.

That is because there is no clear way in which to make an organism with that desired property. As such, the claimed invention is not enabled for the entire scope of the claims.

Response to Arguments Concerning Claim Rejections - 35 USC § 112

Applicant's arguments filed September 25, 2003 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal with regard to the rejection under Written Description:

1. Applicant asserts that, because Applicant has described a method of screening for (and thus identifying) the claimed microorganism, they have satisfied the Written Description requirement by showing they were in possession of the claimed genus of microorganisms.

Applicant's traversal is not convincing for the following reasons:

1. Applicant's own argument pontificates the lack of a written description with regard to the broadly claimed invention. Applicant states that the claimed strains can be identified by a screening process, thus they were in possession of the claimed genus. However, it is unclear how one can possess something that still must be identified. The salient feature of the rejection is that there is no correlation between a structural feature of a microorganism (i.e., a genetic alteration) that necessarily results in the desired function (i.e., the ability of the strain to both survive/grow and produce glutamic acid at saturated levels of glutamic acid). A method of screening for microorganisms does not bridge the gap between structure and function, and essentially represents a method of trial and error experimentation. As such, Applicant's argument is insufficient to establish that the Written Description requirement has been met.

Applicant's arguments filed September 25, 2003 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal with regard to the rejection under Enablement:

1. Applicant asserts that, because Applicant has described a method of screening for (and thus identifying) the claimed microorganism, they have satisfied the Enablement requirement by showing the claimed microorganism can be obtained by the screening method.

2. Applicant provides several references describing the enzymes involved in glutamic acid biosynthesis in a number of microorganisms. Applicant summarizes the references, and concludes by alleging that other microorganisms besides an *Enterobacter* can represent the claimed invention.

Applicant's arguments are not convincing for the following reasons:

1. As stated before concerning the rejection under Written Description, a method for identifying microorganisms is not equivalent to a method for "making and using" a microorganism. The fact of the matter is that neither the specification nor the prior art establishes a structure-function relationship for the ability of a microorganism to survive and further produce glutamic acid in a medium where the concentrations of glutamic acid are at an inhibitory concentration (i.e., its saturation concentration). .Without this structure function relationship, the skilled artisan could not take another microorganism as a starting material, and convert it into one that has the ability to survive and further produce glutamic acid in a medium where the concentrations of glutamic acid are at an inhibitory concentration (i.e., its saturation concentration). Therefore, the skilled artisan cannot make and subsequently use the claimed microorganism without undue and

unpredictable experimentation (i.e., randomly screening for an organism with the desired activity).

2. None of the references cited refers to a structural feature of a microorganism that confers the ability of a microorganism to both survive/grow and produce glutamic acid at saturated levels of glutamic acid, therefore none of the references can be used to overcome the unpredictability associated with the claimed invention. Again, in order to make and subsequently use the claimed microorganisms, the skilled artisan must be able to take a structural feature (i.e., a gene(s)) from a microorganism and confer upon a different microorganism the desired property associated with the structural feature. This is not present in either the instant specification or the prior art. What the prior art provided herein describes is the genes that are involved in glutamic acid biosynthesis; however, these genes are not relevant to the ability to survive/grow and produce glutamic acid at already saturated concentrations of glutamic acid.

In response to Applicant's arguments, it is reiterated that the instant specification and the prior art fails to disclose a structural feature that confers upon a microorganism the ability to survive/grow and produce glutamic acid at already saturated concentrations of glutamic acid. In the absence of such a structural feature, the skilled artisan cannot make any microorganism that has such a desired property. Instead, the skilled artisan would be left to random screening and experimentation to determine if any given microorganism retained the desired function; therefore the broad scope of the claims lacks enablement.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

> has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-10, 14 and 17-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Moriya et al. (US 6,331,419; see entire document; henceforth Moriya). **This is a new rejection not necessitated by amendment.**

Moriya describes the *Enterobacter agglomerans* strain AJ13355 (see for example column 3, line 54 to column 4, line 58) and AJ13356 (see for example column 7, line 63 to column 8, line 28). Since these strains are those exemplified in the instant specification, they must necessarily have the ability to survive/grow and produce glutamic acid at already saturated concentrations of glutamic acid. Furthermore, Moriya describes further modifying the microorganism to express a plethora of enzymes (such as citrate synthase (CS) or glutamate dehydrogenase (GDH)) involved in the biosynthesis of glutamic acid to further improve the production of glutamic acid (see for example column 5, line 10to column 7, line 16). As such, Moriya anticipates the claims to the microorganisms. Moriya further teaches culturing these microorganisms for the purpose of producing glutamic acid, wherein the culture conditions include a pH range of 4.0 to 8.0 (see for example column 8, line 59 to column 9, line 2). Importantly, the pH range includes a range at which glutamic acid is precipitated (i.e., one that is

not more than pH 5.0). Also included in the medium in which the microorganisms are grown are a carbon source and an organic acid (see for example column 8, lines 34-58). As a result, Moriya also anticipates the claimed methods of producing glutamic acid.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-13 and 15-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5-8 of copending Application No. 10/077,751 (also PG PUB US 2002/0192772; henceforth '751). Although the

conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are genus claims that are anticipated by the specific claims of '751. Specifically, the instant claims are anticipated by the more narrowly defined claims of '751 which further indicate that the pH be 5.0 or less and where the growth of the organism is not inhibited by the presence of an organic acid (at a concentration of 0.4 g/L or less) which contains 1, 2 or 3 carbon atoms. **This rejection is maintained for the reasons set forth in the previous Office Action.**

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments Concerning Double Patenting

Applicant's arguments filed September 25, 2003 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

1. Applicant has amended the claims of the co-pending application as per the Office's suggestion, and that the limitations now set forth in the co-pending claims are not present in the instant claims. Applicant asserts that the rejection should now no longer apply.

Applicant's arguments are not convincing because the claim of the co-pending application is still a species that anticipates the broad genus of claims of the instant application. First, it is noted that there is nothing on record in the instant application suggesting that Applicant amend the co-pending claims to traverse the instant rejection, and it is not understood

where Applicant has obtained such a suggestion. Additionally, Applicant has simply added limitations to the co-pending claims, making the claim more specific in nature; this does not prevent the claim from anticipating the broader claims of the instant application, which encompass the more specific claims of the co-pending application. It is specifically noted that there is nothing in the claims of the instant specification to exclude the new limitations indicated as being made to the claims of the co-pending application, therefore such limitations are also broadly encompassed by the instant claims. As such, the rejection is maintained for the reasons set forth previously.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636

JAMES KETTER
PRIMARY EXAMINER